

REMARKS

Claims 54-59, 61-67, 69-85, 87-95 and 97-106 are pending. Claim 60 has been canceled without prejudice or disclaimer. Claims 54, 61-64, 65, 69-73, 79, 80, 85, 87-89, 95 and 97-99 are amended. Applicants retain the right to file continuing applications. New claim 107 has been added. No new matter has been added.

Applicants gratefully acknowledge entry of the substitute sequence listing filed on June 23, 2004 and Applicants Amendment and Reply filed on March 18, 2004.

Specification

The specification was amended on June 23, 2004 to add the sequence of the polynucleotide sequence (AF007544) incorporated by reference at page 5 of the specification (SEQ ID NO:2). The specification was also amended to correct the sequence identifier to refer to Genbank accession number AF007544 as SEQ ID NO:2, as sequence identifier, SEQ ID NO:1, had previously been use to identify the sequence in Figure 11 at page 12 of the specification. The addition of this sequence does not constitute new matter since the sequence at page 5 was originally incorporated by reference.

Rejection Under 35 U.S.C. §112, first paragraph

Claims 85, 87-95, 97-106 are rejected under 35 U.S.C. §112, first paragraph (enablement), because while being enabled for (i) *in vitro* embodiments directed to expression of a desired polypeptide sequence when the polynucleotide sequence is operatively linked to the recited PSMA enhancer element and promoter, and (ii) methods of treating prostate cancer wherein the vector used comprises a recombinant expression cassette comprising a polynucleotide sequence encoding an enzyme that converts a prodrug to a toxic drug operatively linked to both an enhancer element obtained form intron 3 of the PSMgene and a promoter element, these claims are allegedly not enabled any other *in vivo* embodiments wherein the claimed regulatory elements are used to direct expression of a given heterologous sequence. Applicants traverse this rejection for reasons of record and to the extent it applies to the herein claimed invention. Claim 85 has been amended to recite a method of directing expression of a coding sequence in a prostate cell, and is thereby enabled as asserted in the Office Action. Claim 95 has been amended to recite a method of treating prostate cancer and is thereby enabled as asserted in the Office Action. In addition, new claim 107 has been added to cover *in vitro*

expression of a coding sequence. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection Under 35 U.S.C. §112, first paragraph

Claims 64 and 72-73 are rejected under 35 U.S.C. §112, first paragraph (written description) as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. In particular, the Office Action reiterates its previous rejection to the use of the phrase “regulatory element”. Applicants traverse this rejection to the extent it applies to the herein claimed invention. Claims 64, 72 and 73 have been amended to recite “enhancer element obtained”. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection Under 35 U.S.C. §112, second paragraph

Claims 60-63, 69-71, 79-84, 87-89 and 97-99 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point and distinctly claim the subject matter which Applicants regard as the invention. Applicants traverse this rejection for at least the following reasons.

Claim 60 has been deleted and therefore the rejection is rendered moot. As a result, claims 62 and 63, originally depending from claim 60 have been amended to depend from claim 54.

Claims 61-63, 69-71, 79-84, 87-89 and 97-99 are rejected for assertedly not reciting a particular set of hybridization conditions and therefore, are open to interpretation by the skilled artisan. Applicants traverse the rejection for reasons of record and to the extent it applies to the herein claimed invention. Claims 61, 69-71, 79-80, 87-89 and 97-99 have been amended, as suggested by the Office Action, to recite high stringency option (i) in the paragraph bridging pages 8 and 9 of the specification. Any rejection to claims 62 and 63 is obviated in view that they never depended from claim 61 and now depend from claim 54. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection Under 35 U.S.C. §102

Claims 54-56, 60-63, 65, 67, 69-71 and 79-83 are rejected under 35 U.S.C. §102 as allegedly being anticipated by O'Keefe et al. Applicants traverse the rejection for at least the following reasons. O'Keefe et al. do not teach the recombinant polynucleotide and expression cassette of the claimed invention comprising an operably linked enhancer element. Claims 54 and 65 have been amended to recite an enhancer element "operably linked" to the nucleic acid sequence encoding a heterologous gene, and a promoter, respectively. In view of the herein claimed invention, Applicants respectfully submit that the rejection is obviated for dependent claims 55-56, 61-63, 67 and 69-71. Moreover, O'Keefe et al. do not teach the isolated nucleic acid molecule having enhancer activity of the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Entry of the Amendment and Reply and favorable consideration are respectfully requested.


To the extent necessary, please grant any extension of time deemed necessary for entry of this communication. Please charge any deficient fees, or credit any overpayment of fees, to Deposit Account 500417.

Respectfully submitted,

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